

# EXHIBIT K



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/754,337	04/05/2010	Denise Demarais	578568015US4	6524

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MEDTRONIC VASCULAR, INC.  
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EXAMINER
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SMITH, KAITLYN ELIZABETH

ART UNIT	PAPER NUMBER
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3739

NOTIFICATION DATE	DELIVERY MODE
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08/29/2013

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 12/754,337	<b>Applicant(s)</b> DEMARAIS ET AL.	
	<b>Examiner</b> KAITLYN SMITH	<b>Art Unit</b> 3739	<b>AIA (First Inventor to File) Status</b> No

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2013.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 31-50 is/are pending in the application.  
5a) Of the above claim(s) 37-40 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 31-36 and 41-50 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 05 April 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

#### Certified copies:

- a) ☐ All    b) ☐ Some    c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 3) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/17/2011, 05/25/2012, 02/05/2013, 2 IDS</u><br><u>05/23/2013, 05/29/2013 and 06/04/2013.</u> | 4) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. It is noted that claim elements that use the word "means" are presumed to invoke 35 U.S.C. 112(f) or 35 U.S.C. 112 (pre-AIA), sixth paragraph except as otherwise indicated in the Office Action. Similarly, claim elements that do not use the word "means" are presumed not to invoke 35 U.S.C. 112(f) or 35 U.S.C. 112 (pre-AIA), sixth paragraph except as otherwise indicated in the Office Action.

### ***Information Disclosure Statement***

2. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

### ***Election/Restrictions***

3. Applicant's election without traverse of Species L in the reply filed on 23 April 2013 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of 35 U.S.C. 112(a):  
(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claim 45 is rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement.**

6. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no description as to how the signal generator is configured to create a reverse thermal gradient between the blood vessel wall and the target neural tissue. In fact the specification points to the focusing as the way to produce the claimed reverse thermal gradient.

7. The following is a quotation of 35 U.S.C. 112(b):  
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 44 and 47 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.**

9. Claim elements “means for controlling the thermal neuromodulation therapy delivered to the target neural fibers using data from the temperature sensor” and “means for controlling the application of ultrasound thermal treatment via the thermal element based on the monitored parameter” are limitations that invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. However, the written description fails

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to disclose the corresponding structure, material, or acts for the claimed function. There is no disclosure of the corresponding structure or materials that perform the claimed function

Applicant may:

(a) Amend the claim so that the claim limitation will no longer be interpreted as a limitation under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function, without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function applicant should clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

***Claim Rejections - 35 USC § 103***

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10. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**11. Claims 31, 32, 34-36, 41-44 and 46-50 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over US 5,368,591 to Lennox (Lennox) in view of US 6,254,598 B1 to Edwards et al. (Edwards).**

12. Lennox teaches heated balloon catheters (title) comprising a catheter sized and shaped for intravascular placement within a renal blood vessel of a human patient (Col. 7, lines 10-12), electrical contacts (22 and 24) located inside inflatable balloon (8) and a temperature sensor (26) wherein the catheter is configured to vary between a reduced delivery and retrieval configuration and an expanded deployed configuration (see entire document). The balloon catheter is connected to RF power supply (50) and temperature control circuitry (38) such that data from the temperature sensor is used for feedback control of the heating (Fig. 4 and claims) where the temperature is set by the user. However, Lennox does not teach one or more ultrasound transducers positioned along the catheter.

13. Edwards teaches an analogous apparatus (10) comprising a catheter (18), an inflatable balloon (25) and one or more ultrasound transducers (22 and Col. 6, lines 45-64) positioned along the catheter. The one or more ultrasound transducers may be positioned within the inflatable balloon (Figs. 2d and 2e) and may be attached directly to the inflatable balloon (2d and 2e). Edwards teaches an ultrasound signal generator (Col.

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6, lines 45-64 as well as a temperature sensor (29 and Col. 9, lines 14-27) where data from the temperature sensor is used for feedback control (Col. 9, lines 14-27) and an imaging transducer (Col. 12, lines 29-37). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the ultrasound energy of Edwards for the RF energy of Lennox as an obvious substitution of one known heating means for another. Similarly, the inclusion of the imaging would allow for the energy to be correctly directed to the tissue to be treated.

14. Regarding the ultrasound transducer being concave so as to self-focus the ultrasound energy, it is known that transducer elements may employ a concave shape to focus ultrasound energy. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized a concave shaped transducer element to focus the ultrasound energy as desired (see for example US 5,588,434).

15. Regarding the sensor comprises an imaging transducer, it is known to convert ultrasound imaging data into temperature imaging data for ultrasound treated patient tissue to monitor the ultrasound treatment (see for example US 2003/0013971).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized an imaging transducer as the sensor as this is a known way to monitor the ultrasound treatment.

16. Regarding the functional language of the catheter being configured to transmit ultrasound waves to renal neural fibers outside the vessel to thermally induce of target fibers while protecting non-target tissue in the blood vessel all from thermal injury and the apparatus configured to deliver high intensity focused ultrasound, a recitation of the



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intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

**17. Claims 31-33, 35, 36, 41-44 and 46-50 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over US 5,368,591 to Lennox et al. (Lennox) in view of US 6,954,977 B2 to Maguire et al. (Maguire).**

18. Lennox teaches heated balloon catheters (title) comprising a catheter sized and shaped for intravascular placement within a renal blood vessel of a human patient (Col. 7, lines 10-12), electrical contacts (22 and 24) located inside inflatable balloon (8) and a temperature sensor (26) wherein the catheter is configured to vary between a reduced delivery and retrieval configuration and an expanded deployed configuration (see entire document). The balloon catheter is connected to RF power supply (50) and temperature control circuitry (38) such that data from the temperature sensor is used for feedback control of the heating (Fig. 4 and claims) where the temperature is set by the user. However, Lennox does not teach one or more ultrasound transducers positioned along the catheter.

19. Maguire teaches an analogous circumferential ablation apparatus (title) the apparatus including a catheter (201) with a fluid inflatable balloon (212) proximate one or more ultrasound transducers positioned along the catheter (Col. 17, line 56-Col. 18, line 11 and Fig. 2) and an ultrasound signal generator (Col. 17, line 56-Col. 18, line 11). The inflatable balloon comprises an acoustically transmissive portion and an

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acoustically reflective portion (Col. 39, lines 23-44). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the ultrasound energy of Maguire for the RF energy of Lennox as an obvious substitution of one known heating means for another. This is particularly true as Maguire teaches that many structures can perform the heating (Col. 17, line 56-Col. 18, line 11).

20. Regarding the ultrasound transducer being concave so as to self-focus the ultrasound energy, it is known that transducer elements may employ a concave shape to focus ultrasound energy. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized a concave shaped transducer element to focus the ultrasound energy as desired (see for example US 5,588,434).

21. Regarding the sensor comprises an imaging transducer, it is known to convert ultrasound imaging data into temperature imaging data for ultrasound treated patient tissue to monitor the ultrasound treatment (see for example US 2003/0013971).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized an imaging transducer as the sensor as this is a known way to monitor the ultrasound treatment.

22. Regarding the functional language of the catheter being configured to transmit ultrasound waves to renal neural fibers outside the vessel to thermally induce of target fibers while protecting non-target tissue in the blood vessel all from thermal injury and the apparatus configured to deliver high intensity focused ultrasound, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

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invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

**23. Claim 45 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lennox and Edwards or Lennox and Maguire as applied to claim 42 above, and further in view of US 5,471,988 to Fujio et al. (Fujio).**

24. Lennox and Edwards or Lennox and Maguire teach the apparatus of claim 42, but not the creation of a reverse thermal gradient. Fujio teaches an ultrasonic diagnosis and therapy system in view the variant of expansion of the balloon (433a) is adjusted for the adjustment in depth, and after the positioning adjustment of the focused point against the treatment region, ultrasonic waves are irradiated into the region (Col. 55, lines 25-36). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the focusing of Fujio in order to select the focal point of treatment. Therefore, this combination also teaches the requirements of a thermal gradient as Fujio allows for selection of the focal point of the ultrasonic energy thereby creating a thermal gradient.

### ***Conclusion***

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN SMITH whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 9:00 a.m. to 5:30 p.m. EDT.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAITLYN SMITH/  
Examiner, Art Unit 3739

/Linda C Dvorak/  
Supervisory Patent Examiner, Art  
Unit 3739